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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,134	10/31/2000	Andrey A. Boukharov	04983.0201.00US00/38-21(5	8935

28381 7590 09/22/2004

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/702,134	Applicant(s) BOUKHAROV ET AL.	
	Examiner Diana B. Johansen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

1. This action is in response to the Amendment filed June 18, 2004. Claims 2-4 have been canceled. Claims 1 and 8-12 are now pending and under consideration. Applicants' arguments have been thoroughly considered, but are not persuasive for the reasons that follow. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

3. In view of the cancellation of claims 2-4, the rejections of those claims under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph are moot.
4. Claims 1 and 8-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility, for the reasons set forth in the Office action of March 19, 2004.

The response traverses the rejection on the following grounds. The response notes that an invention must only provide one utility (or "identifiable benefit"), and argues that Applicants have provided at least one such utility/benefit, citing as an example "use to identify a polymorphism in a population of plants." The response further urges that the specification "discloses several uses for the claimed nucleic acid molecules," which uses are enumerated at pages 6-7 of Applicants' response. The response argues that "Many of these uses are directly analogous to the use of a microscope," which may be used "to identify and characterize the structure of biological

tissues in a sample, cell or organism.” Applicant states that the examiner “suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose” as the claimed molecules. Applicant urges that “there is no requirement of exclusive utility in the patent law,” and states that “Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose.” The response argues that the claimed molecules meet the utility requirement because they “will identify a unique subset of related sequences” which is “specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule.”

Applicants’ arguments have been thoroughly considered but are not persuasive for the following reasons. First, it is acknowledged that 35 U.S.C. 101 requires only a single utility that meets the criteria of being specific and substantial. However, in the instant case, as discussed and set forth in the prior Office action, Applicants’ invention does not possess a utility that actually meets these criteria. In particular, the examiner noted in that Office action that the claims had been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001 (“the Utility guidelines”), and provided the following definition for the term “specific”:

“Specific” - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

The examiner further stated that the utilities asserted by Applicant were general utilities applicable to “virtually any genomic nucleic acid from any plant,” rather than “substantial

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uses that are specific to one or more of the molecules disclosed by applicant.” With particular regard to Applicants’ argument that the claimed invention is useful “to identify a polymorphism in a population of plants,” it is noted that while molecules encompassed by the claims could clearly be used to differentiate, e.g., the particular sequence of SEQ ID NO: 7212 from variants thereof, the same is true of any polymorphic nucleic acid molecule (i.e., any nucleic acid containing a polymorphism could be used to differentiate a variant comprising that polymorphism from other variants of the same molecule that lack the polymorphism). It is well known in the art that genes typically exist in multiple forms, such that some members of a population possess one variant having a particular nucleic acid sequence, while other members of the population possess different variants of the same gene having one or more polymorphisms with respect to the first variant. The number of such molecules is vast, and any variant of a gene (or any fragment thereof comprising a polymorphism) could be used in the same manner asserted by Applicant with respect to the molecules of the claimed invention. With regard to Applicants’ argument that the molecules of the claims may be used as research tools in a manner analogous to a microscope, this argument is not persuasive. Like the other general utilities discussed above, such a general use (in “identifying and characterizing” other nucleic acids) is applicable to virtually any genomic nucleic acid. While it is true that a microscope may be employed in identifying and characterizing tissues, this is also true of numerous types of equipment found routinely in laboratories, including gel electrophoresis apparatus, thermocyclers, vacuum blotters, etc.; all of these items may be used in various ways to achieve the general objective of “identifying and

characterizing" biological tissues. However, a microscope is known to function in a particular way that differentiates it from these other types of equipment, and has a use in specific aspects of identification and characterization of tissues (e.g., visualization of structures) that differs from the specific uses of other types of equipment that are also useful in "identifying and characterizing" tissues. Accordingly, in contrast to the molecules of the claims, a microscope is not merely a member of a large genus of items for which specific functions have yet to be identified, but rather a well characterized piece of laboratory equipment with a specific and substantial use. Applicant has yet to identify such a specific and substantial use for SEQ ID NO: 7212. Regarding Applicant's statement that the examiner "suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose," it is noted that the examiner did not make such a statement, but rather suggested that uses that are generally applicable to any nucleic acid cannot be considered a specific and substantial use for a particular nucleic acid molecule. It is acknowledged that a variety of different types of golf clubs may be used to hit a golf ball. However, this use in performing a specific task (i.e., hitting a golf ball) differentiates golf clubs from other types of athletic equipment (for example, tennis racquets). However, the instant specification does not disclose a substantial use that is specific either to SEQ ID NO: 7212 or, e.g., a group of molecules including SEQ ID NO: 7212 that would differentiate it from, for example, SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, etc. Further, while it is acknowledged that SEQ ID NO: 7212 could be used to differentiate, e.g., complements of SEQ ID NO: 7212 from complements of SEQ ID NO: 1, complements

of SEQ ID NO: 2, etc., such a use is not specific and substantial unless a specific and substantial use for the molecule being detected has been identified. It is again noted that research and experimentation on nucleic acids constitutes a general utility, rather than a specific and substantial “real world” use. See *Brenner v. Manson*, 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion”. A patent is therefore not a license to experiment with the objective of eventually identifying a specific and substantial use for a product or method. Accordingly, Applicant’s arguments are not persuasive, and this rejection is maintained.

5. Claims 1 and 8-12 are also rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the Office action of March 19, 2004.

The response traverses this rejection on the grounds that the rejection of the claims for lack of utility has been overcome for the same reasons detailed in Applicant’s earlier arguments (which arguments were summarized above). Accordingly, the response to those arguments set forth above applies equally herein, and this rejection is maintained.

6. Claims 1 and 8-12 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in the Office action of March 19, 2004.

The response traverses the rejection on the following grounds. The response urges that the use of the terms “comprising” or “having” properly leave the claims “open for the inclusion of unspecified ingredients,” citing *Ex parte Davis* (80 USPQ 448, 450

(BPAI 1948)). The response lists numerous types of variants of SEQ ID NO: 7212 (enumerated at page 14) and asserts that these molecules are described. The response concludes that the claimed molecules meet the written description requirement because “Applicants have disclosed a common structural feature, the nucleotide sequence of SEQ ID NO: 7212” and therefore have met the written description requirement as “elucidated” by the Federal Circuit.

These arguments have been thoroughly considered but are not persuasive for the reasons that follow. First, it is acknowledged that the open language “comprising” and “having” in the instant claims allows for the inclusion of undescribed, “unspecified ingredients.” Further, it is acknowledged that nucleic acid molecules either “having” or “comprising” the nucleic acid sequence of SEQ ID NO: 7212 meet the written description requirement; the basis for the instant rejection is the lack of written description for molecules comprising subsequences of SEQ ID NO: 7212 and complements thereof, as well as molecules comprising nucleic acids less than 100% identical to SEQ ID NO: 7212. However, while Applicants’ response provides a long list of additional molecules and variants of SEQ ID NO: 7212 that are in fact encompassed by the claims, the response does not provide any arguments or reasoning as to why all of these additional molecules – which differ from SEQ ID NO: 7212 in structure, and are not disclosed as sharing a common function with SEQ ID NO: 7212 – do in fact meet the written description requirement. Further, as these additional molecules do not in fact comprise SEQ ID NO: 7212, these additional molecules do not in fact share a “common structural feature,” as asserted by Applicant. Applicant’s arguments are

therefore not persuasive, as the claims fail to meet the written description requirement for the reasons set forth in the prior Office action. Accordingly, this rejection is maintained.

Claim Rejections - 35 USC § 112, second paragraph

7. In view of the cancellation of claims 2-4, the rejection of those claims under 35 112, second paragraph is moot.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

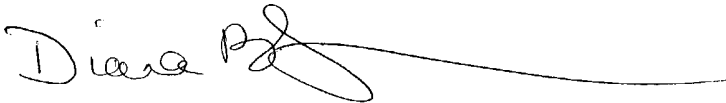
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long, horizontal, slightly wavy line extending to the right.

Diana B. Johannsen
Primary Examiner
September 20, 2004